This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. **CERTIFICATE NUMBER:** 14-R-0027

CUSTOMER NUMBER: 123

FORM APPROVED
OMB NO. 0579-0036

Avant Immunotherapeutics, Inc.
119 Fourth Avenue
Needham, MA 02494

Telephone: (781) -433-0771

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY **(Attach additional sheets if necessarv or use APHIS Form 7023A)**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs	0	150	10	37	197
7. Hamsters					
8. Rabbits	41	87	286	0	373
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

Print)

(b)(6), (b)(7)c

DATE SIGNED
11/20/07

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 14-R-0027

2. Number 37 of animals used in this study.

3. Species (common name) GUINEA PIG of animals used in the study.

4. Explain the procedure producing pain and/or distress.

SEE ATTACHED

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

SEE ATTACHED AND BELOW

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency FDA CFR 21 CFR PART 610.11

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Details of the procedures creating the pain and distress experienced by animals in Category E.

The 37 Guinea Pigs listed in Category E were involved in experiments developing a General Safety Test procedure as mandated by the FDA.

The General Safety Test is a release assay specified in the Code of Federal Regulations (CFR) to be performed on every lot of biological products intended for administration to humans (21 CFR, Part 610.11). The purpose of the test is to detect extraneous toxic contaminants that may be present in a particular lot of product. The CFR mandates the test must be conducted essentially as follows. A volume of 0.5 mL of the reconstituted product is injected intraperitoneally (i.p.) in at least two mice. In addition, a volume of 5.0 mL of the reconstituted product is injected i.p. in at least two guinea pigs. A sample "passes" the test if 1) the animals survive 7 days, 2) they do not exhibit any unexpected responses in the 7-day test period, and 3) they weigh no less at the end of 7 days than at the time of injection. Unfortunately, the General Safety Test, while mandated, is incompatible with an orally administered live, attenuated bacterial vaccines like those developed at AVANT Immunotherapeutics. Reconstituted vials of some of our vaccines can contain approximately 10^9 CFU/ mL and would be lethal if injected i.p. in mice or guinea pigs at the prescribed doses. Furthermore, such lethality would manifest in the absence of an extraneous toxic contaminant(s).

To allow AVANT to comply with federal law and be able to release orally administered live, attenuated bacterial vaccines, AVANT was directed by the FDA to modify the General Safety Test per a 2/3/94 FDA memorandum. This memorandum guided us to dilute our product to a point just below what would fail a General Safety Test, based on the intrinsic i.p. toxicity of the product. It was recommended that this maximally tolerated dilution would be determined with 3 different lots of material, and then this dilution should then be used for all future General Safety Tests.

The modified General Safety Test Protocol was then determined as follows. Groups of guinea pigs and groups of mice were established. Increasing amounts of reconstituted vaccine, was administered i.p. to the guinea pigs in log dilution increments. Increasing amounts of reconstituted vaccine was also administered i.p. to mice in log dilution increments. Animals were monitored daily and weighed at the beginning of the study and at the end of the study. Based on the result from this study, we established the maximal dose of vaccine that may be administered to mice and guinea pigs that would pass the General Safety Test. Unfortunately in the course of these experiments some animals that received a dose of vaccine above the maximally tolerated (passing) dilution suffered some pain and distress, which could not alleviated with appropriate drugs. The 37 guinea pigs in Category E received such doses.

The doses established in these preliminary studies were used in the General Safety Test which was performed to release vaccine.